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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,489	04/30/2001	David Bach	20816/2	2352

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EXAMINER

CHEU, CHANGHWA J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 12/17/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,489

Applicant(s)

BACH ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-6, 12-14, 16, 18-20, 26-32, 34, 41, 43, 45, 47, 53, 56, 58, 64-81 is/are pending in the application.
- 4a) Of the above claim(s) 64-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-6, 12-14, 16, 18-20, 26-32, 34, 41, 43, 45, 47, 53, 56, 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment filed on 9/29/2003 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 1, 7-11, 21-25, 38-40, 42, 44, 46, 48-52, 54-56, 57, 59-61, 62-63 are cancelled.
2. Claims 64-81 are added to the instant application.

Election/Restrictions

1. Applicants' election of Group II, claims 2-6, 12-14, 16, 18-20, 26-32, 34, 41, 43, 45, 47, 53, 56, 58, with traverse is acknowledged. Applicant argues that group II and V are identical inventions, and they are not separate species nor different genus, therefore applicant is entitled to rejoin group II and V for examination. Applicant's argument has been considered but appears not persuasive. As indicated in the Restriction/Election Office Action, the feature of "a polymer film waveguide core layer for propagating light, and a polymer waveguide cladding layer in contact with the core layer containing a plurality of nanowells" in invention II, is not required by the claims of group V. Similarly, the feature of "having a plurality of fluorescent labels chemically attached to molecules in the test sample, and a means for causing said test samples with said chemically attached fluorescent labels to contact the bound molecules in the nanowells" in invention V, is not required by the claims of other groups. Therefore, group II and V are distinct and unrelated under MPEP § 806.05(e).

2. Newly submitted claims 64-81 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly added claims 64-81 are duplicates of original group V, claims 38-40, 42, 44, 46, 48-52, 54-55, 57, 59, 60-61, 62-63, which are patentably distinct from group II.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

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on the merits. Accordingly, claims 64-81 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Currently, claims 2-6, 12-14, 16, 18-20, 26-32, 34, 41, 43, 45, 47, 53, 56, 58 are under examination.

4. The Restriction Requirement is still deemed proper and is therefore made **FINAL**.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 2, line 13, “a polymer waveguide cladding layer in contact with said core layer containing a plurality of nanowells for holding said test sample” is vague and indefinite. It is unclear where the “plurality of nanowells” located, either within the cladding layer, or in the core layer.

With respect to claim 55, “said nanowells have dimension” is vague and indefinite. It is unclear what kind of dimension applicant refers to, e.g. depth, radius, or diameter.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

8. Claims 2-6, 12-14, 16, 18-20, 27-32, 34, 41, 43, 45, 47, 56 are rejected under 35 U.S.C. 102(a) as being anticipated by Walt et al. (US 6210910).

Walt et al. teach a biosensor array comprising a plurality of nanowells formed at the distal end of individual fibers with an imaging optical fiber array. (See abstract and Figure 1) The optical fiber serves as the function of waveguide, i.e. propagating light wave, for detection of chemical and biological materials by binding of analyte specific binding partners located in the nanowells. (Figure 1 and Figure 5) The structure of the Walt et al. biosensor comprising a light detector optical coupling the fiber in contact with the cladding layer where sample of interests can be placed in the cladding layer for light detection. (Col. 6, line 32-36; Col. 11, line 32-40; Figure 1 and Figure 5) The dimension of the nanoarray taught by Walt et al. is either 75 micron or 25 micron. (Col. 10, line 10-20) Walt et al. also teach use various light sources, such as fluorescence, polarization light and/or UV light source for detection purposes. (See Table 6 and Table 7)

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. in view of Liu (US 5444807).

Walt et al. reference has been discussed but does not explicitly teach using a microseparation process. Nevertheless, it is a well-known knowledge in the art to have microseparation prior to analyze target substance, i.e. coupling HPLC to samples for more purity. For instance, Liu teaches improving fluorescence sensitivity using a microseparation HPLC detector for detecting analyte in the fluid. (Col. 4, line 17-21; Col 5, line 36-45) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide modified device of Walt and Pantano et al. with the microseparation column as taught by Liu, in order to improve the sensitivity of the detection.

12. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walt et al. in view of Karras (US 5862276)

Walt et al. reference has been discussed but does not explicitly reveal the materials used for cladding layer. Karras teaches that cellulose acetate butyrate is a commercially available cladding material and widely used in the study of photolithograph. (Col. 1, line 10-15; Col. 5, line 15-25) Therefore, it would have been obvious to one of ordinary skill

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in the art at the time the invention was made to have provided Walt et al. with the cellulose acetate butyrate as the cladding materials as taught by Karras since it is well-known in the art as a choice for cladding material.

Response to Applicant's Arguments

13. Applicant's arguments with respect to claims 1-2 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

14. No claim is allowed.

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.


Jacob Cheu

Examiner

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December 5, 2003



LONG LE
SUPERVISOR, PATENT EXAMINER
ART UNIT 1641

12/15/03